

## MAMMOMAT Balance

SP

### Installation and Start-up

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| Chapter | Page | Revision |
|---------|------|----------|
| all     | all  | 03       |

## Document revision level

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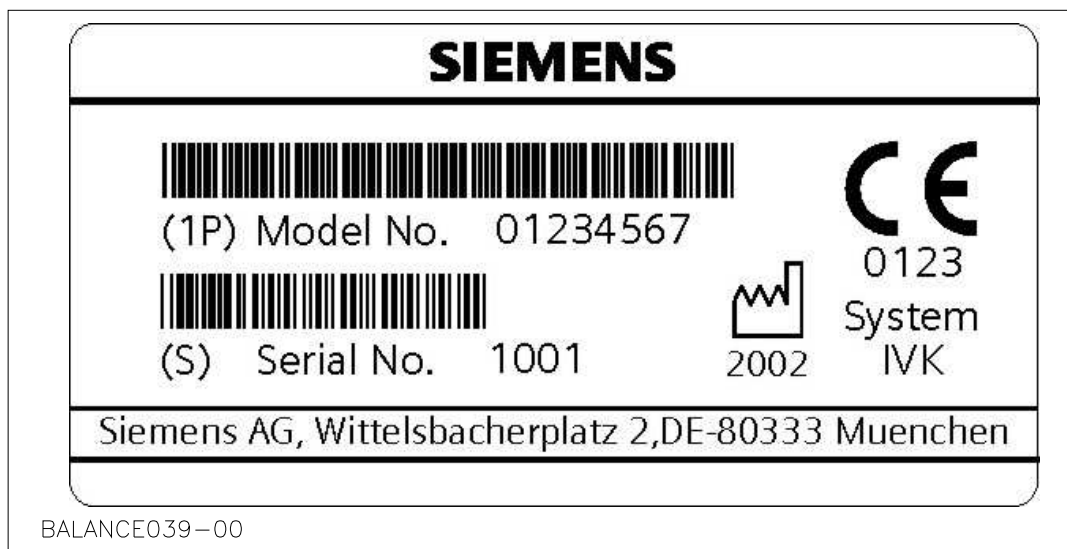
## Identification

### Device classification

Directive 93/42/EEC for Medical Devices

**MAMMOMAT Balance belongs to Class IIb.**

The identification label is placed on the back of device and a true copy of it is also placed inside on it.

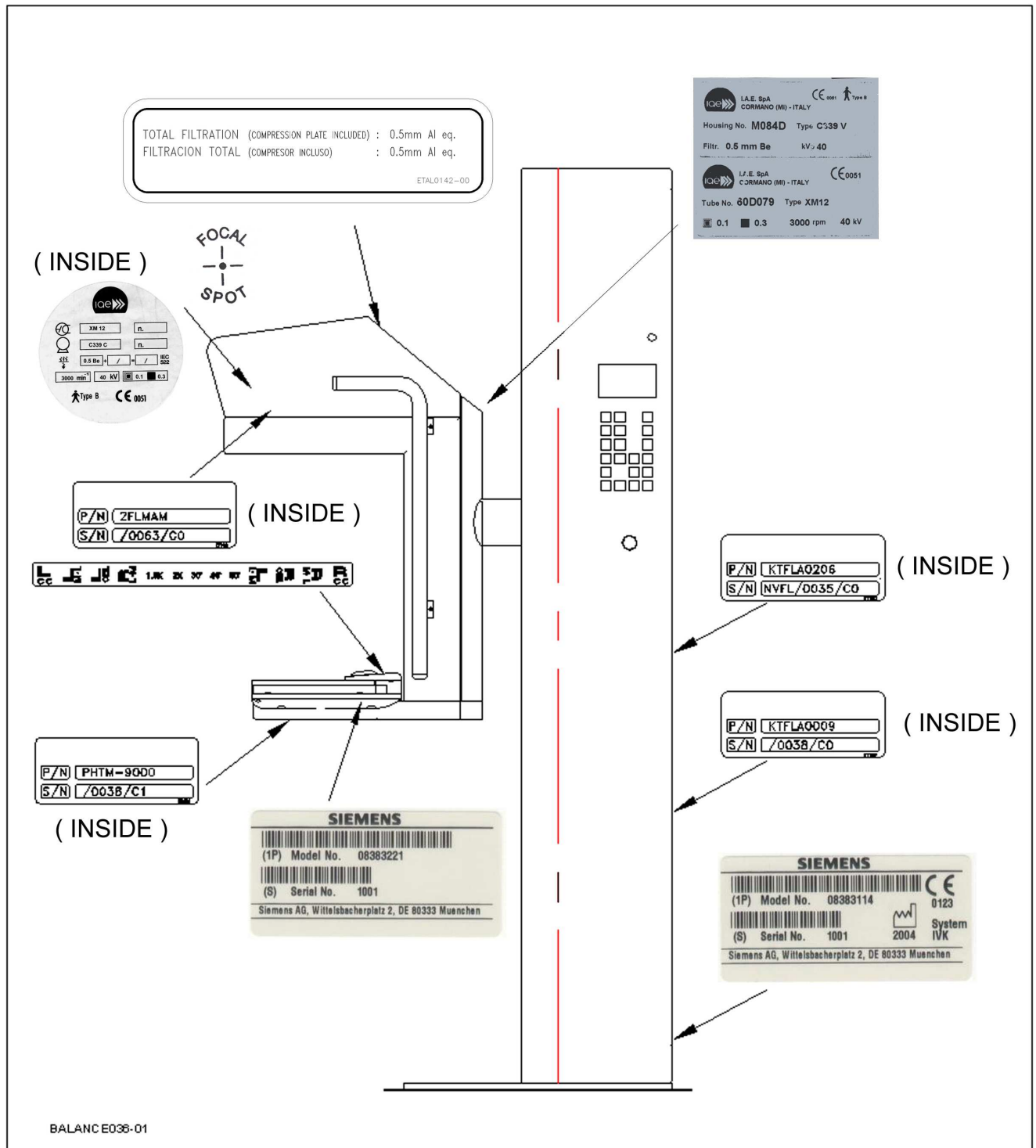


### IEC 601-1 Standard

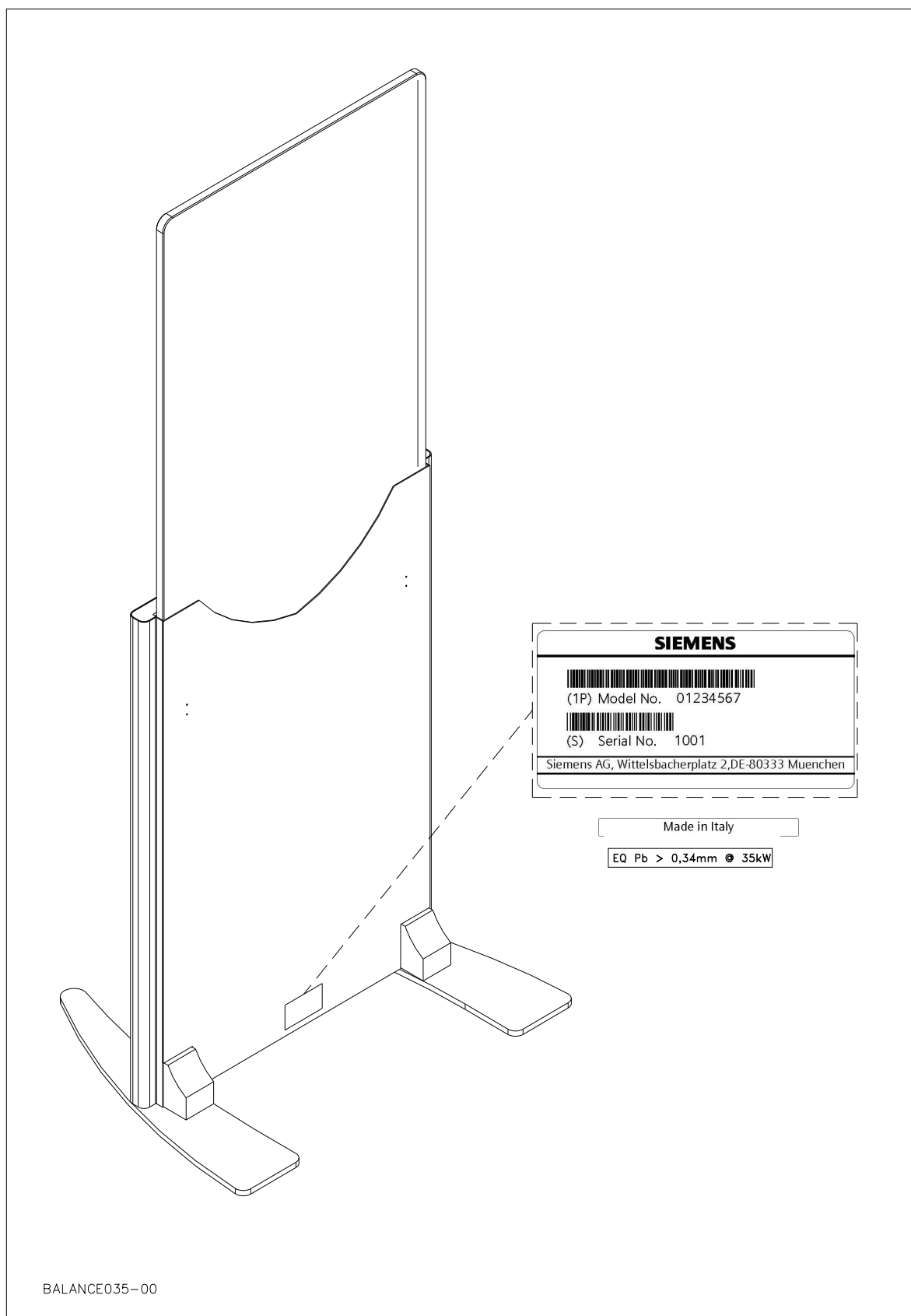
**MAMMOMAT Balance belongs to Class I type B.**

**The installation have to be done according to IEC 60601-1-1.**

## Identification Labels

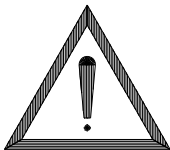


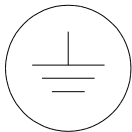
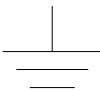

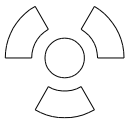


**CE**  
**0123**



# Identification

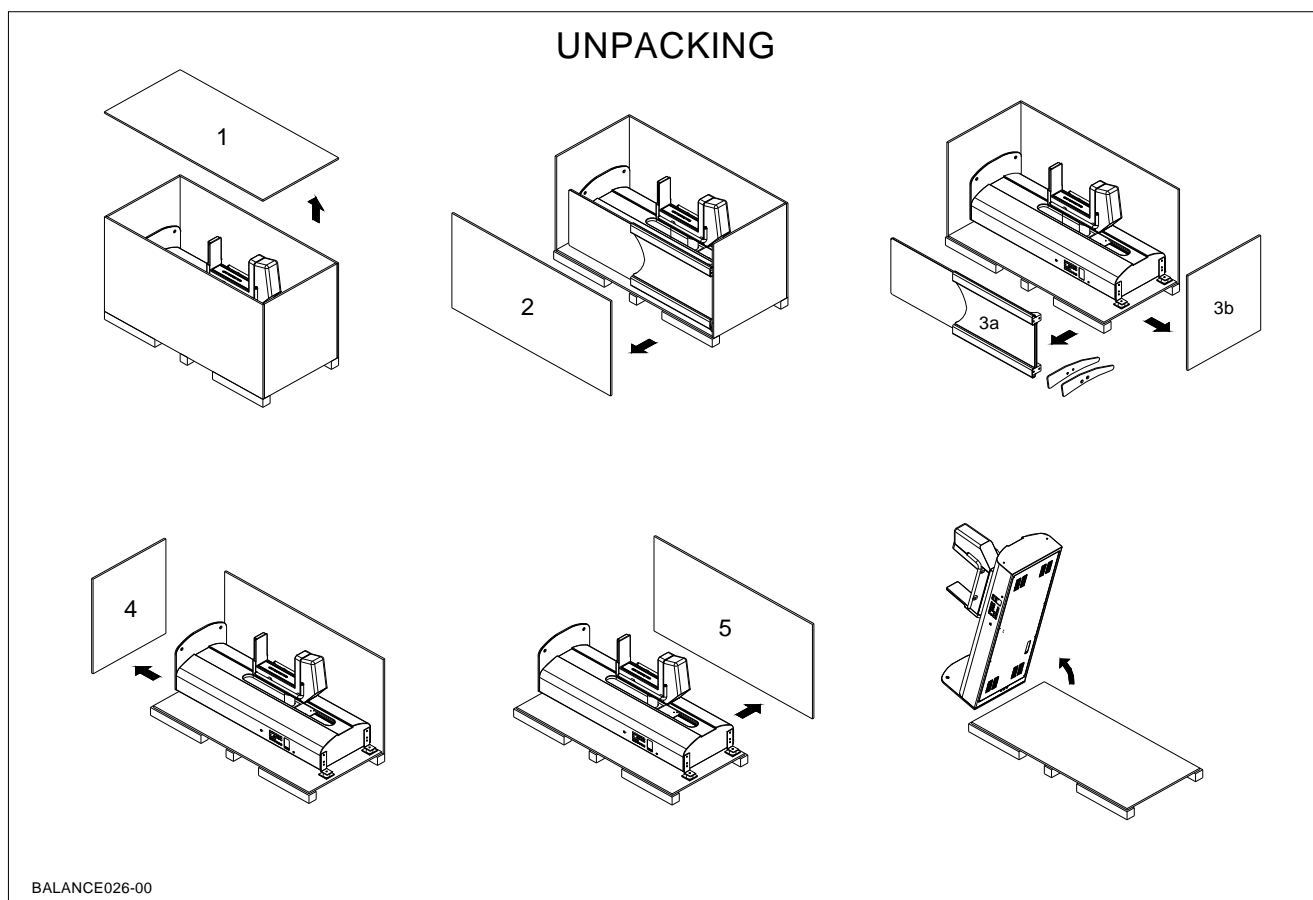
The meaning of symbols appearing on the plate and on some components of the machine is specified in the following table.

| SIMBOLS   | CEI-IEC<br>STANDARDS DEFINITIONS  |
|---|-----------------------------------|
|    | 348<br>Caution, see documentation |
|    | 878-02-02<br>Type-B Equipment     |
|   | 878-01-14<br>Alternate Current    |
|  | 417-5019<br>Protective earth      |
|  | 417-5017<br>Functional earth      |
|  | 878-03-01<br>High tension         |
|  | 878-03-03<br>Ionizing radiations  |

OPE16ING.DWG



## Unpacking



### CAUTION

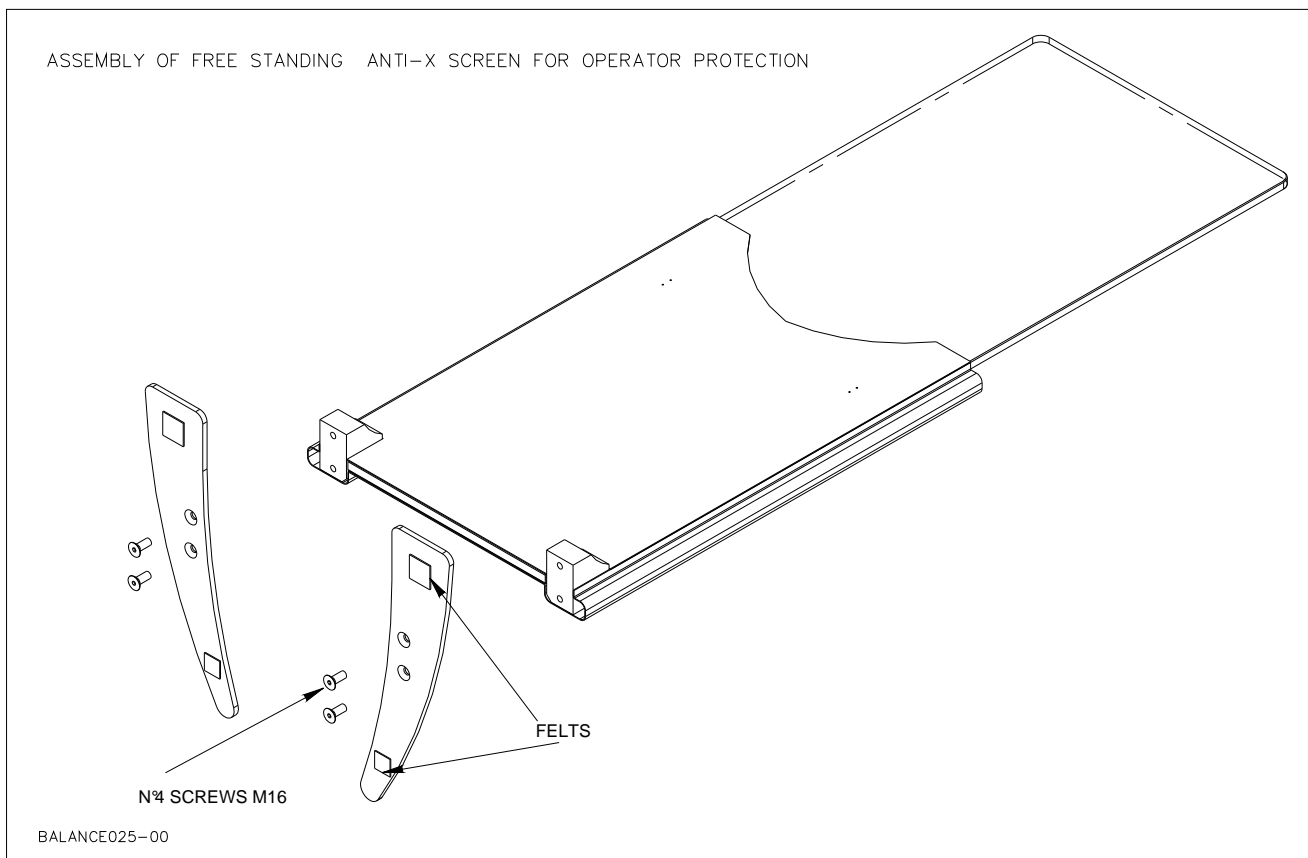
**Wear safety footwear!**

### WARNING

**Do not apply forces to c-arm when moving the unit out of the box and during final location placement**

## Installation

### Anti-X screen assembly



In case of risk of dew, once the equipment has been unpacked, wait for at least 24 hours before applying voltage, thus enabling it to reach a thermal equilibrium with the surrounding environment.

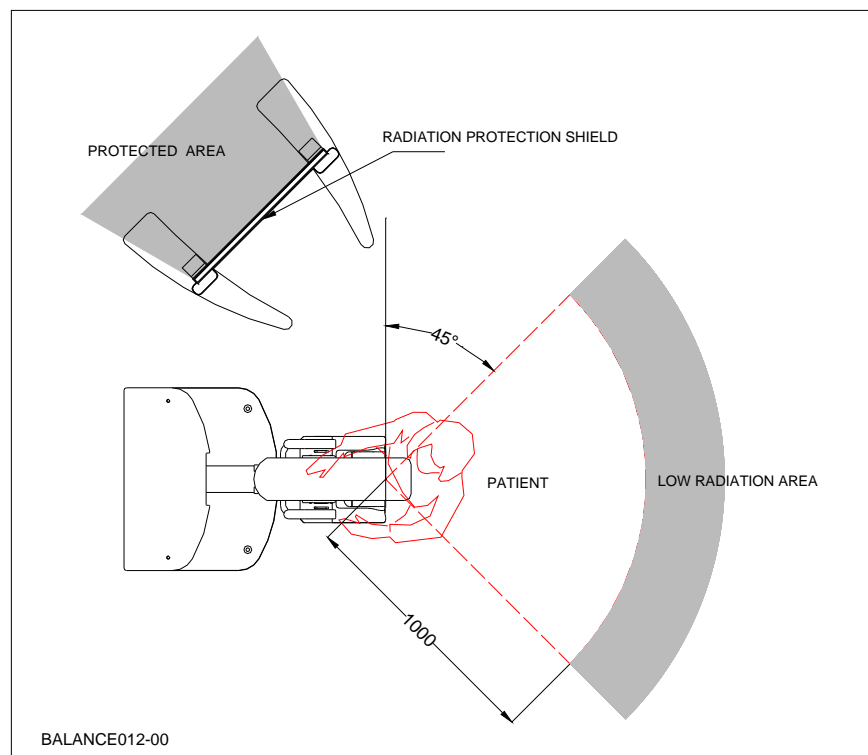
## Ambient storage conditions (while packed)

- temperature: -20°C/+70°C
- relative humidity: 10% ÷ 100%
- atmospheric pressure: 500 hPa ÷ 1060 hPa

## Ambient working conditions

- temperature: +10°C/+40°C
- relative humidity: 10% ÷ 75%
- atmospheric pressure: 700 hPa ÷ 1060 hPa

## Anti-X screen and unit placement



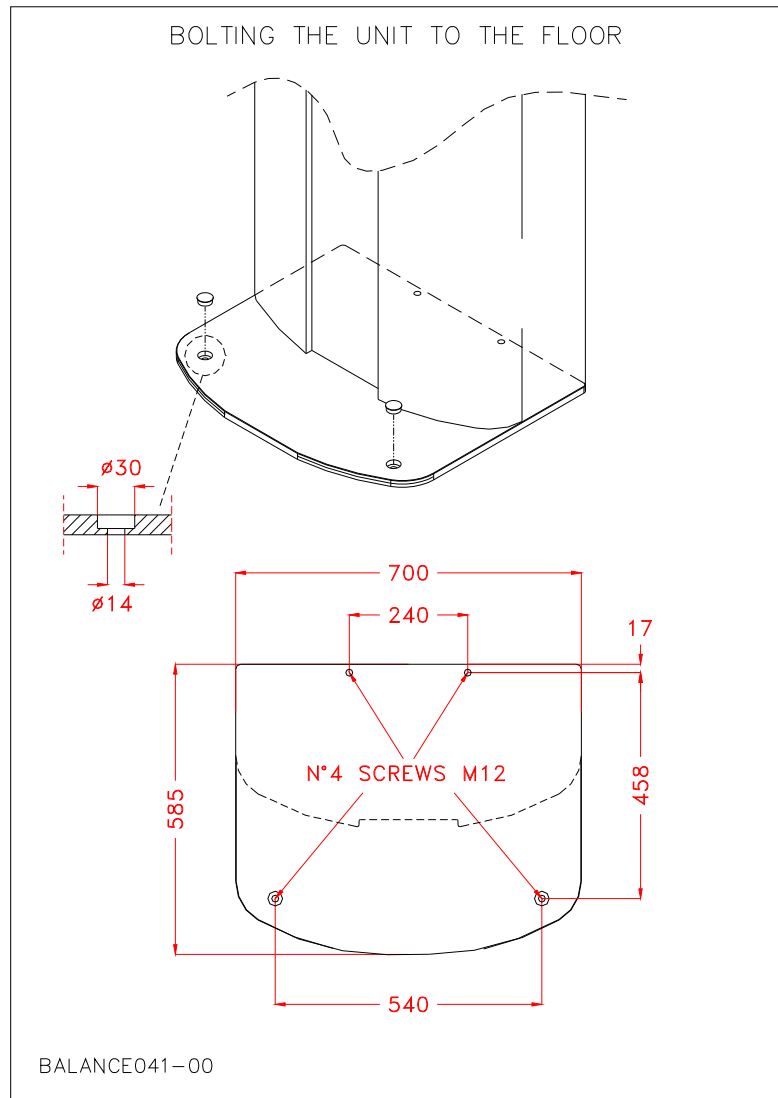
The operator protection screen must be placed so that:

- The patient is on view throughout examination time;
- Control panel indications are on view;
- Patient and emergency cut off buttons are immediately accessible.

It's essential that protection glass and operator be close to the unit, control panel side.

## Bolting the stand to the floor

Should a permanent fastening to the floor be required due to local regulations (for example in earthquake areas) or due to the quality of the floor covering, the stand can be secured to the floor by means of safety dowels or screws. When bolting the stand to the floor, the fixing screws shall pass through the hollow levelling screws. After bolting the stand put in place plastic covers on the external fixing holes.



1. Position the stand and mark out appropriate fixing holes on the floor, using the base plate as a template or mark floor according to the above dimensional drawing.

### NOTICE

**The stand shall be secured with at least four screws each (two on either side).**

2. Drill the holes, insert dowels, position the stand, insert screws and tighten the screws to 10 Nm. Dowels and screws must be supplied by local technician, compatible with stand fixing holes (see above drawings) and according to floor characteristics and local laws regulations.

### CAUTION

**Make sure that the screws do not come in contact with any conductive material such as reinforcing iron.**

## Protective measures

It is very important that any intervention in the equipment will start with disconnecting it from the mains by means of wall mounted circuit breaker. Before removing or inserting any of the printed circuit board, switch OFF the equipment.

In the following list all dangerous parts are highlighted, read it carefully before to touch any internal part.

For location of the listed parts refer to "Backside view main internal components location" and "C-Arm components location" in the next pages.

### WARNING

**If the system is only switched OFF at the control panel , line voltage is still present at the followings:**

Mains input terminal blocks.  
Fuses F1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12  
Main contactor TLR1 and emergency cut off buttons PB2 and PB3  
Line filter FL1  
PCB 03-186 and related parts: Solid state Relay RY1, resistor R1

### WARNING

**Voltage higher than 60Vac is present on :**

Terminal M3  
Transformers TF155, TF165 and their connected parts  
C-arm driving gear motor MT1 and travel-ends MW1, MW2  
Rotating anode starter 92-074 and capacitors C5, C6  
Tube Rotating Anode Cable and supply connections

### WARNING

**After shut down of the system, there may still be dangerous voltage up to 550Vdc on inverter power supply. Voltage decreases to zero by means of bleeder resistors in not less than 5 minutes due to capacitor size, energy stored is still dangerous if short to ground occurs when It's less than 60Vdc and till when capacitors are not fully discharged.**

Rectifier bridges PD1, PD2  
Capacitors block C1, 2, 3, 4  
Inverter block and electrical connection to High Voltage generator

### WARNING

**High-voltage 20÷35 kV is present on:**

High Voltage generator  
High voltage cable  
X-ray Tube

### CAUTION

**Printed Circuit Boards contain electrostatic highly sensitive components requiring particular care in their handling (ground before making contact and place only a conductive surface.**

**CAUTION**

To prevent accidental triggering of High Voltage and X- Radiation output x-ray pushbutton has Dead Man function by which H.V. generator is disconnected by CPU if push button is not intentionally pressed.

For more safety during intervention:

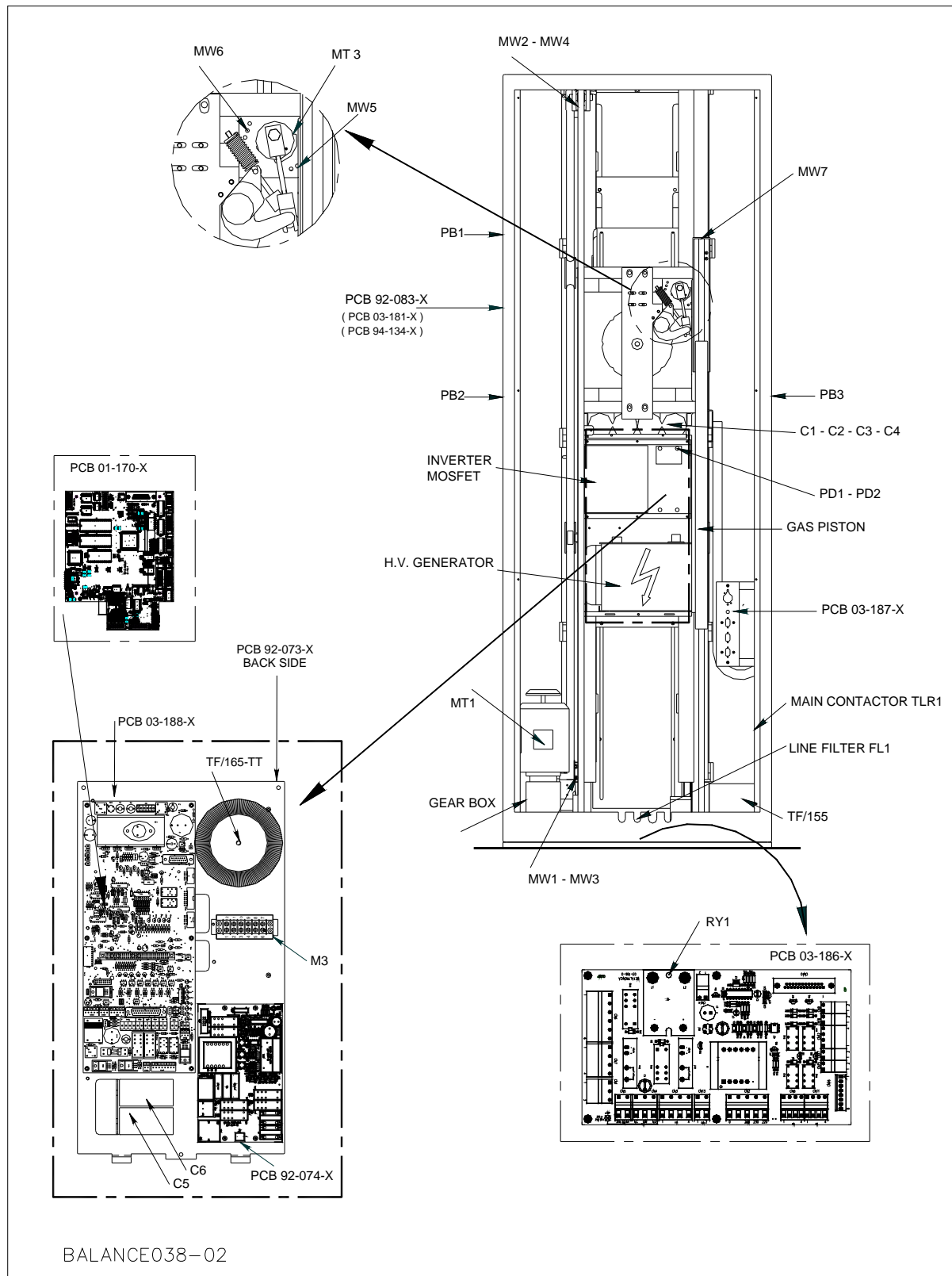
- 1) DEMO MODE can be selected by means of DIP 3 SW1 PCB 01-170
- 2) Fuses F6, F9 can be removed and Inverter voltage monitor disabled by means of DIP2 SW2 set to ON. Vdc across C1,2,3,4, inverter and H.V. transformer will be zero after discharging time.

## Delay times between two exposures

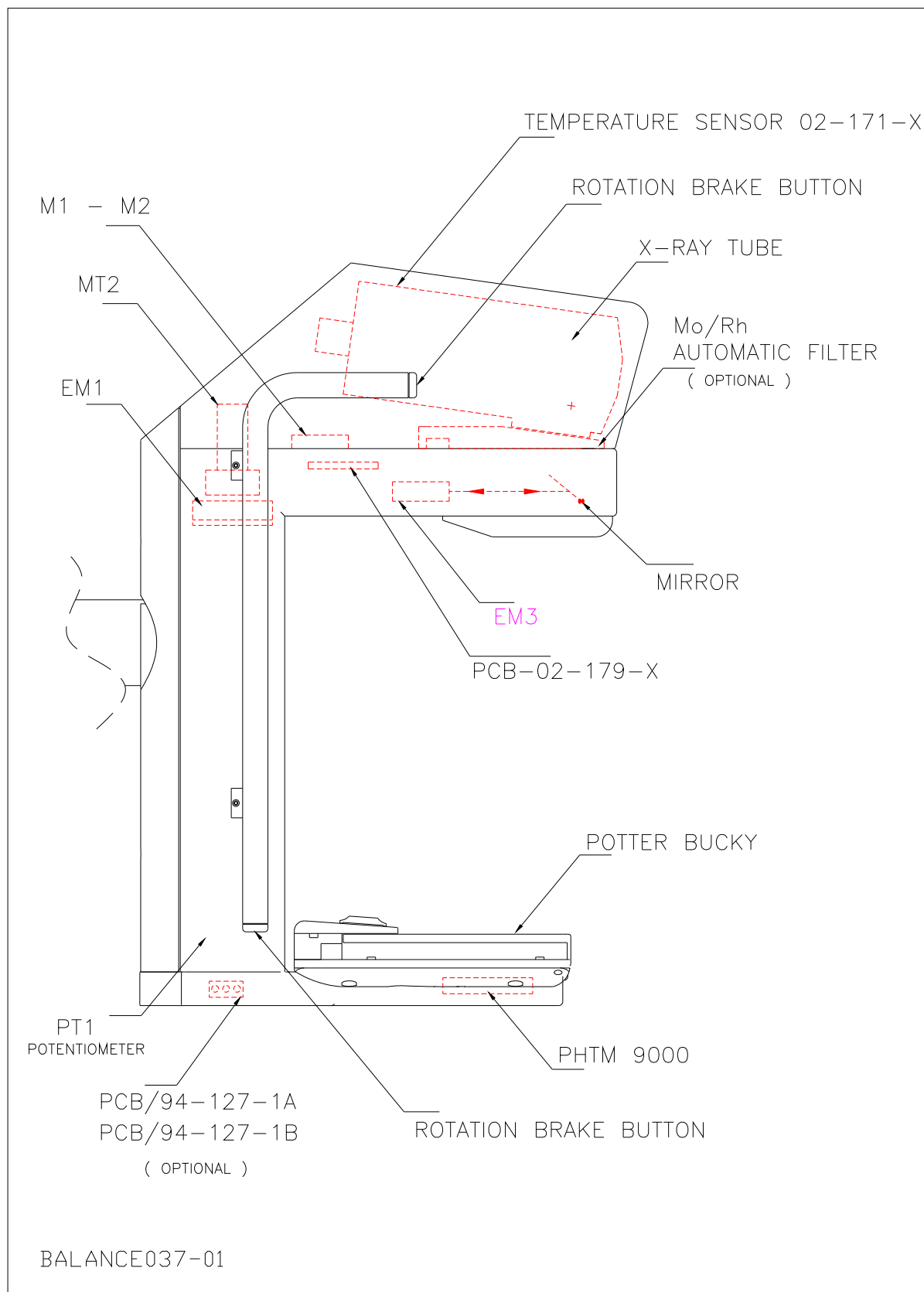
Delay times listed below must be followed in order to prevent the tube from overheating.

| Exposure mAs value | Delay time between two exposures |
|--------------------|----------------------------------|
| mAs 100            | 15 seconds                       |
| mAs 200            | 30 seconds                       |
| mAs 300            | 45 seconds                       |
| mAs 400            | 60 seconds                       |
| mAs 500            | 75 seconds                       |

## Backside view main internal components location



## C-Arm components location



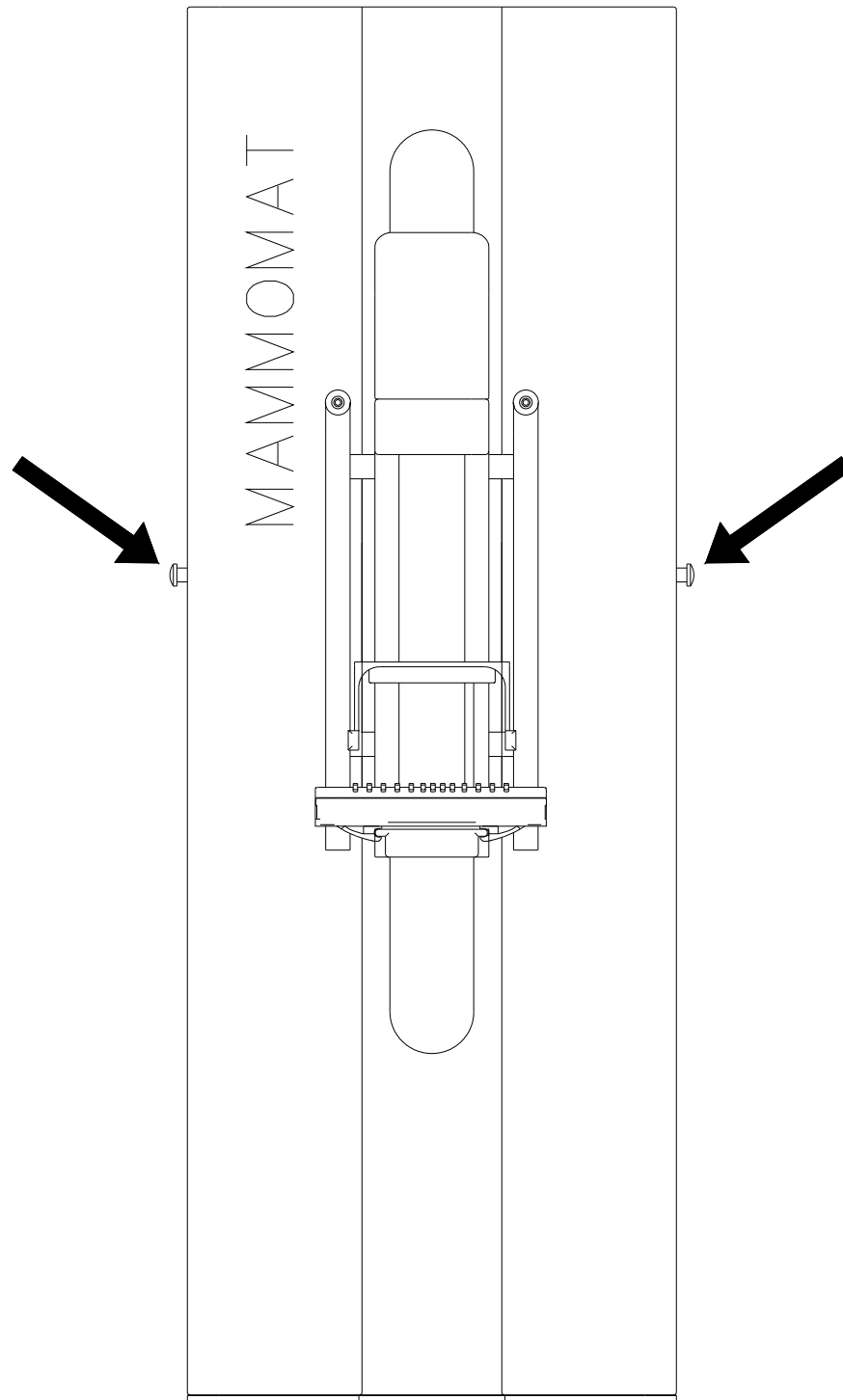


## Emergency Stop/Shutdown Switches

If an equipment malfunction causes an emergency situation, which would involve a hazard for the patient, the operator or for the equipment itself, press one of the two red emergency stop/shutdown switches on the unit. This switch will then immediately disconnect the whole system, all unit drives will be switched off, all movements will be interrupted as well x-ray emission, decompression is automatically assured and patient gets free.

The button may be released (by turning it clockwise) only if the cause of danger has been clearly recognized and eliminated.

In this case, the system must not be put into operation again. Customer service must be notified.



BALANCE040-00

## Power line connection

### WARNING

The unit is supplied with single phase Mains input with :

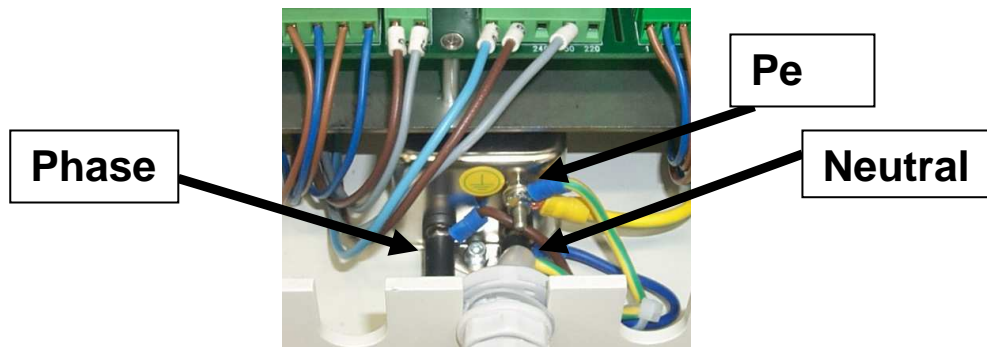
phase / neutral / protective earth

If available Mains is:

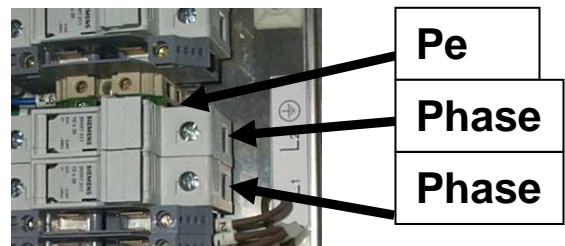
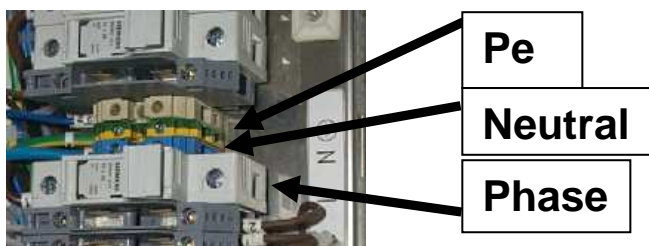
phase / phase / protective earth

blue terminal block for Neutral conductor connection must be replaced with a fuse holder and same fuse rating of the pre existing one for phase conductor connection.

Power line cable is connected to EMC filter input where no change is necessary depending on Phase/Neutral or Phase/Phase configuration.



The following changes are only referred to internal wiring and not power line cable connection.



### CAUTION

For single-phase mains with Phase / Neutral connection, make sure that the neutral conductor of the Mains is connected to terminal N.

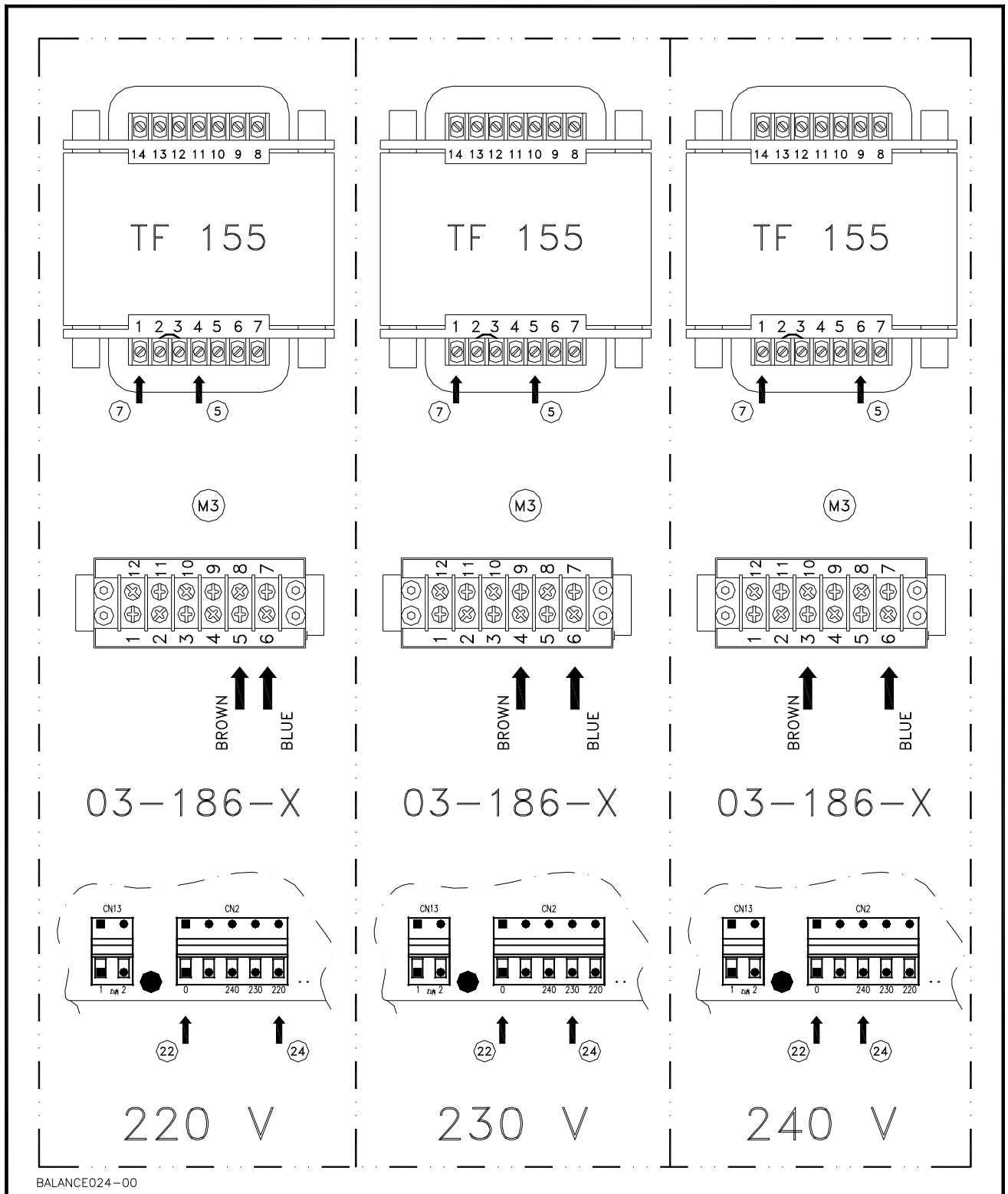
### WARNING

Protective Earth connection must be checked by qualified electrician with appropriate instrument and procedure according to local applicable laws regulations.

### CAUTION

Voltage selector is originally configured for 230Vac Mains. Others 220 or 240 must be configured according to the following wiring diagram

## Voltage selector



## Line Voltage check

After changing Voltage selector, check voltages with DVM across each one of the above points.

## Line frequency adaptation

No frequency adaptation is requested other than for Rotating Anode Starter protection circuit. Original calibration is for 50Hz line frequency, if available line frequency is 60Hz refer to specific procedure in Start-up SPB7-115.815.01....

## Measuring the line resistance

1. Remove fuse F1
2. Connect line resistance meter to fuse holders F1
3. Mains supply "ON".
4. Carry out measurement.
5. Mains supply "OFF".

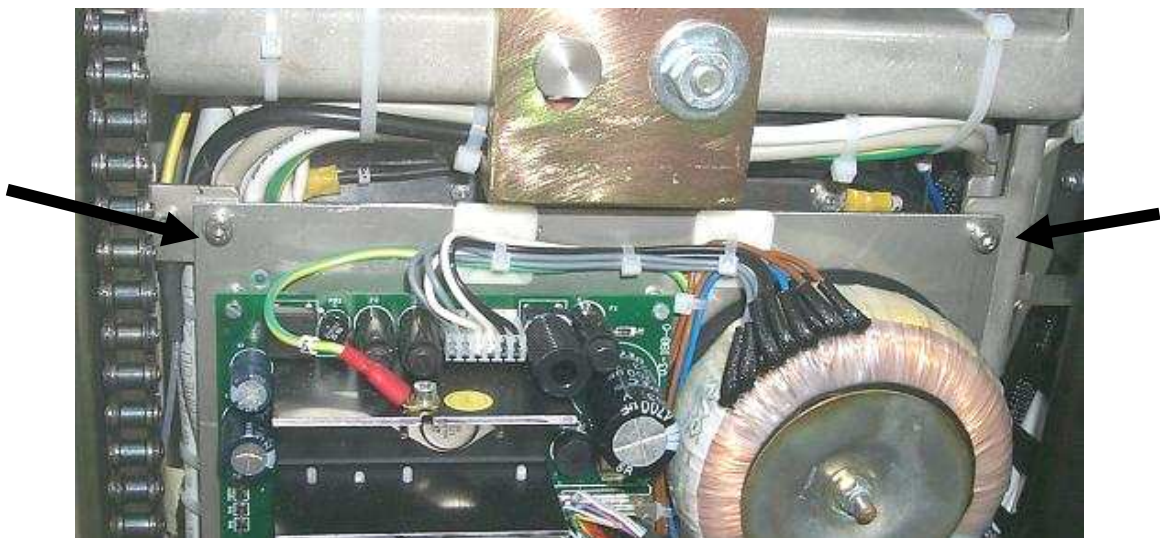
To achieve full output, the resistance measured must not exceed the following value:

0.50  $\Omega$  at 230 V

If the above value is exceeded, general malfunction can occur, refer to qualified electrician to improve line characteristics.

## Service position panel

Switch off the system. Open the screws (see arrows in the picture below) and open panel.

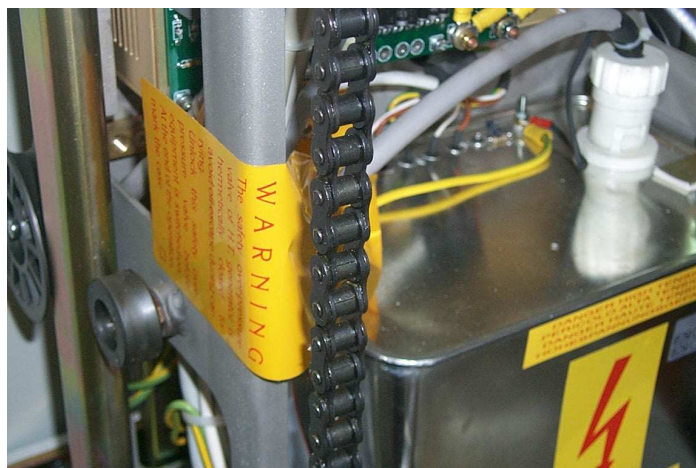


## H.V. generator tank vent valve opening

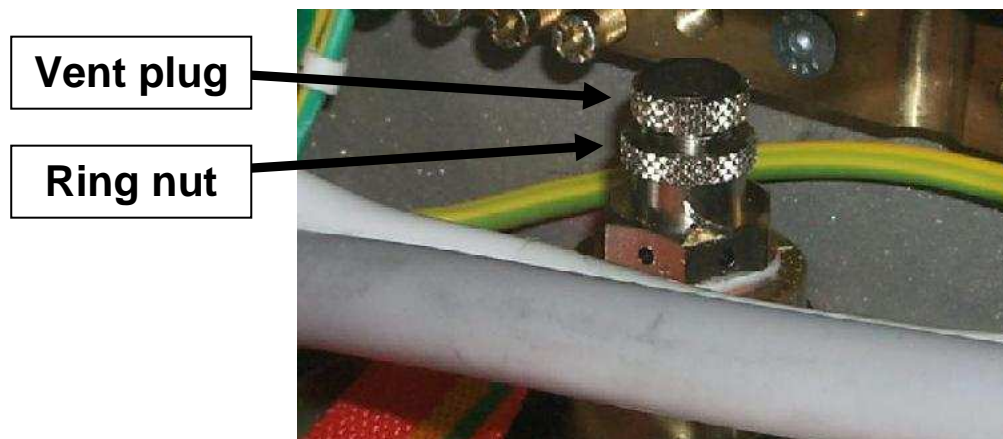
Before unit operation, open H.V. generator tank vent valve for ventilation.



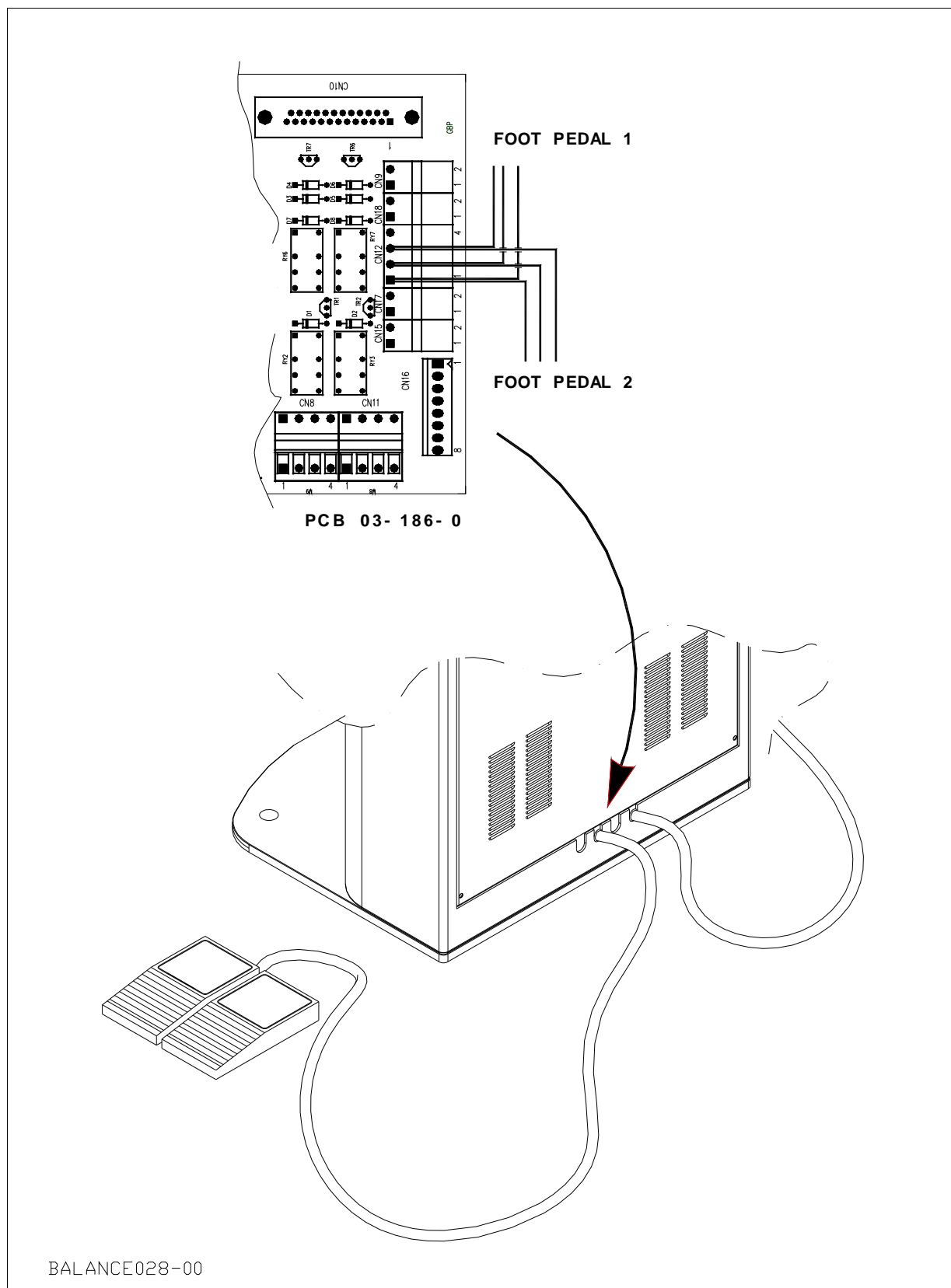
To access it, open service panel and locate valve with yellow label.



Unscrew vent plug of about one or two turns, and secure it with ring nut. If the vent plug is hard to unscrew, it is already secured by the ring nut. So you have first to unscrew ring nut, then unscrew vent plug and finally screw ring nut.



## Foot pedal connection





## Door safety switch, if present

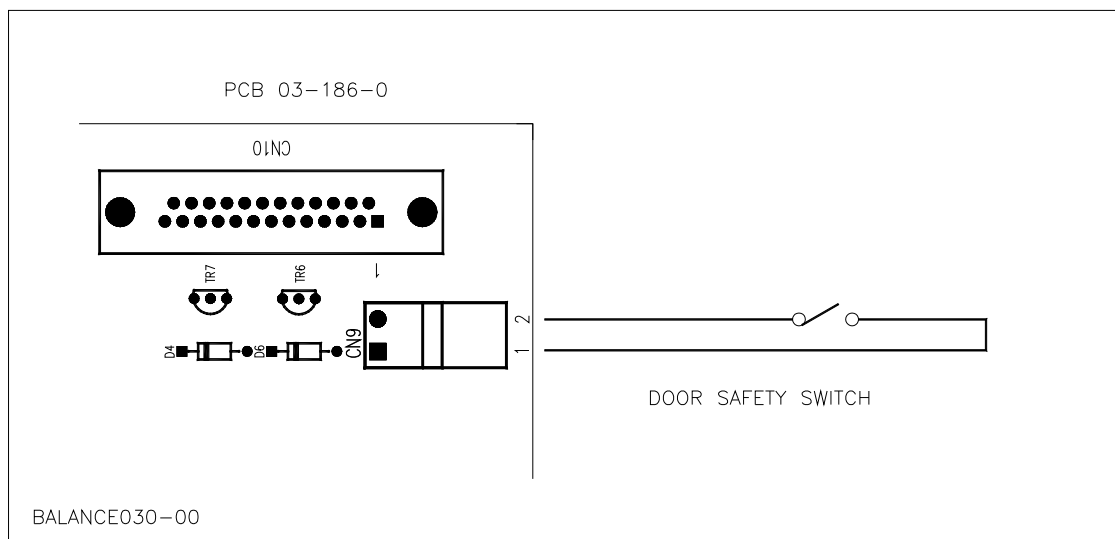
Input for Door Safety Switch is provided at CN9 PCB 03-186.

Any attempt to start exposure sequence while the door is open will cause the alarm message :

**DOOR OPEN**

on the display. Exposure doesn't start.

Opening the door during exposure will have no effect to avoid partial exposure and unusable image.



### NOTICE

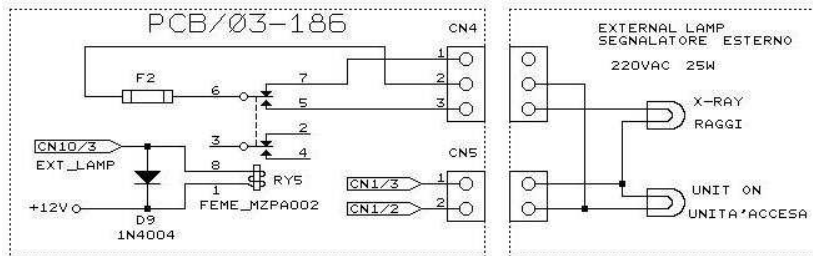
If switch is not connected/used CN9 pins MUST be shorted.

### NOTICE

Low voltage, low current contactors are recommended.

## External lamp, if present

Output connection for external indicator lamp is provided at service board 03-186 CN4, CN5 according to the following schematic.



For example

### NOTICE

**Circuit is protected by fuse F2, DO NOT USE LAMPS EXCEEDING 25 W.**

Different wiring. Voltage free contact is available at CN4, CN5 MUST remain disconnected.



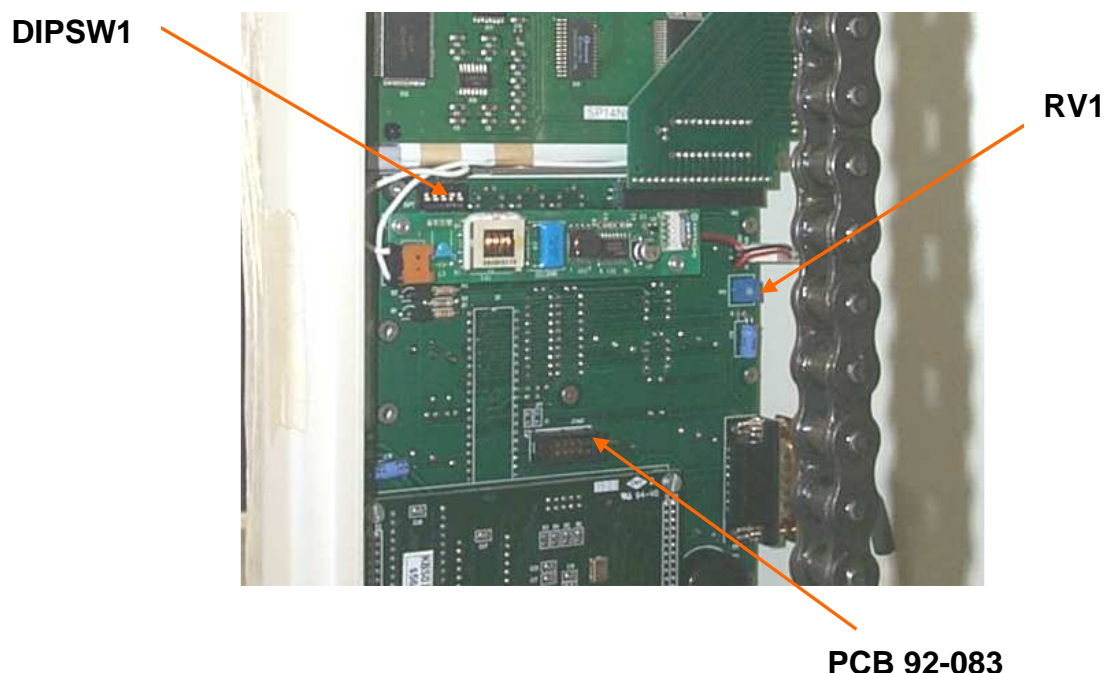
## Start-up

Start up sequence can be initiated only if room temperature is no more than 10°C higher than the temperature of the unit to avoid dew.

AEC linearity calibration can only be carried on after that the unit has reached room temperature.

## LCD contrast adjustment

Display contrast depends on ambient temperature, adjust for best contrast by means of RV1 of PCB 92-083 after that unit has reached room temperature.



## Alarm messages language selection

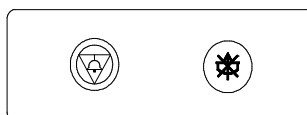
### DIPSW1

| 1   | 2   | 3   | 4   | Language   |
|-----|-----|-----|-----|------------|
| OFF | OFF | OFF | OFF | Italian    |
| ON  | OFF | OFF | OFF | French     |
| OFF | ON  | OFF | OFF | English    |
| ON  | ON  | OFF | OFF | German     |
| OFF | OFF | ON  | OFF | Spanish    |
| ON  | OFF | ON  | OFF | Polish     |
| OFF | ON  | ON  | OFF | Turkish    |
| ON  | ON  | ON  | OFF | Portuguese |

## Date and time setting

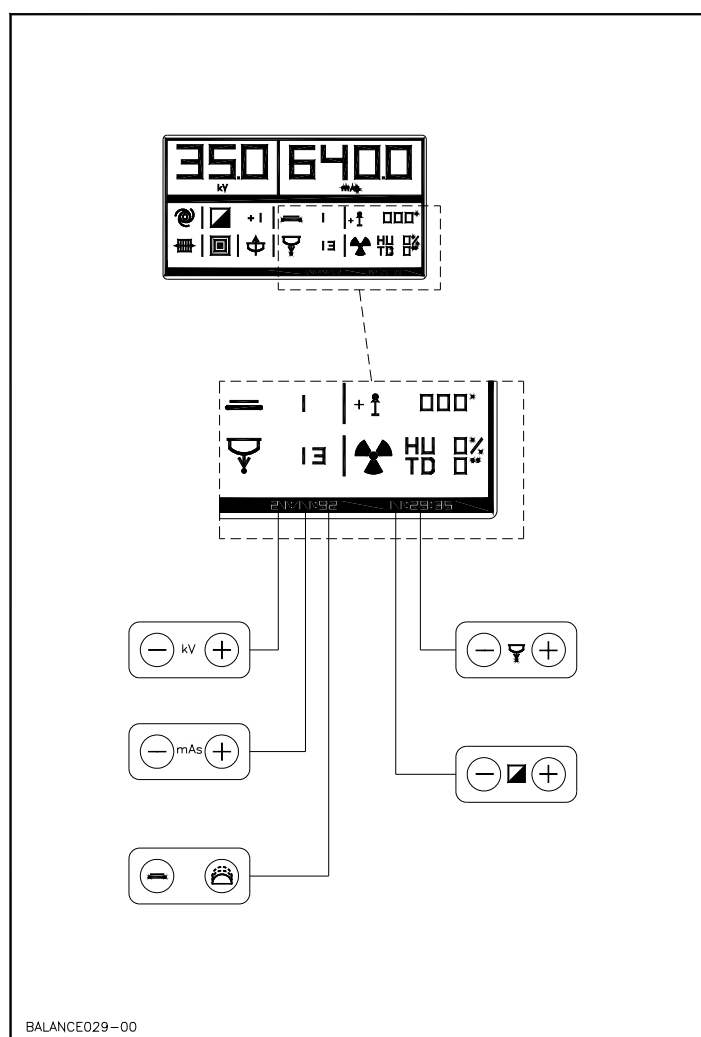
The following steps must be carried out when adjusting the display date and time:

To access Date and Time setting mode push and keep pressed the two pushbuttons:

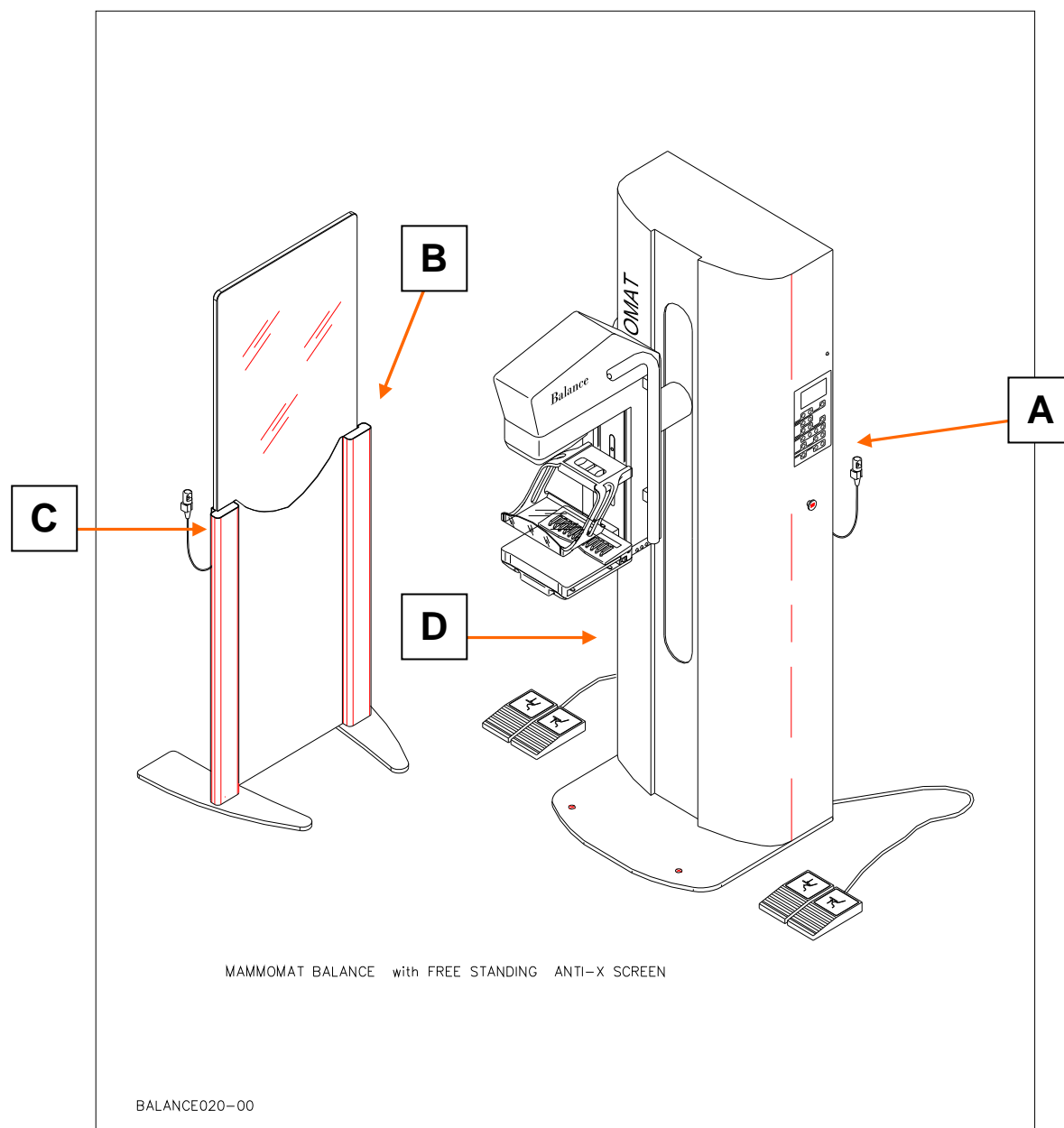


Date and Time can be adjusted by means of the following push buttons:

|         |                                      |
|---------|--------------------------------------|
| Day     | KV +/-                               |
| Month   | mAs +/-                              |
| Year    | film screen selection / AEC position |
| Hour    | manual density +/-                   |
| Minutes | compression force +/-                |



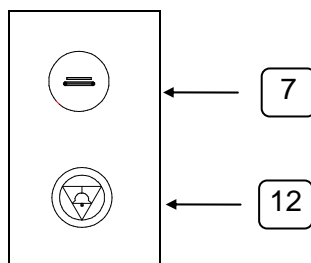
## X-ray pushbutton holder placement



X-ray pushbutton holder can be assembled at position A, B or C by means of two screws. The plug must be inserted in PBRX socket at position D.

## Service menu

If buttons 7 and 12 are held down together, the Service Menu is displayed:



and the following technical information and unit configuration can be seen on the display :

| SIEMENS AG          |               |            |  |
|---------------------|---------------|------------|--|
| CPU 01-170          | F2=OK         | F4=OK      |  |
| SW1 12345678        | SW2 12345     |            |  |
| INVERTER Vdc (in) = | XXX           | LV= OK     |  |
| Filament            | 92-073        | >> PASS << |  |
| Rotating Anode      | 92-074        | >> PASS << |  |
| FIRMWARE REV        | BAL__ XX      | TUBE       |  |
| Tube Housing kJ     |               | 25°C       |  |
| n. XXXXX            | Last Exposure |            |  |

### CPU 01-170 fuses status

F2= (+15Vdc) F4= (+24Vdc)

### CPU 01-170 Dip Switches configuration

#### SW1

- DIP1 = ON = anode current calibration mAH
- DIP2 = ON = anode current calibration mAL
- DIP3 = ON = DEMO mode
- DIP4 = ON = X-Ray interruption (grid movement) disabled
- DIP5 = ON = AEC Deata Plus freeze
- DIP6 = OFF = unused
- DIP7 = ON = compression force calibration
- DIP8 = ON = Automatic Mo/Rh filter enabled

#### SW2

- DIP1 = ON = C-arm brake excluded for SERVICE
- DIP2 = ON = bypass of INVERTER supply check
- DIP3 = ON = max compression force 200 N
- DIP4 = OFF = unused
- DIP5 = OFF = unused

Note: change in SW2 are effective only when technical menu is open and new configuration can be seen on the screen or after initialization due to Power On or return from Alarm.

No change to Dip switch configuration is normally requested for Start Up or installation except for :

## Demo Mode

SW1 DIP3 = ON = DEMO mode

Full functions in Manual Mode are available with simulated x-ray exposure.

Automatic Mode functions can be selected on the control panel but no simulated x-ray exposure is possible.

## Compression force

Depending on local regulations maximum compression force can selected to 150 or 200N, default compression force is 150N ( index range 1÷15).

## Filament Board status

PASS means that PCB 92.073 is operative and filament is OK

FAIL means that PCB 92-073 is defective or filament is open.

## Rotating anode starter status

PASS means that PCB 92.074 is operative

FAIL in stand by means that PCB 92-074 is defective.

## Inverter Vdc power input

Monitor of DC input voltage to inverter of H.V. generator, typical voltage is around 550Vdc.

## Inverter low voltage supply status

Fuse F2 PCB 94-132 (Inverter Control Board).

## Firmware revision and x-ray tube model

Reference of unit configuration and future upgrade.

## Tube housing HU level

HU tube assembly in % depending on tube housing current temperature, if ambient temperature > 25 °C it is > Zero even if tube has not yet been operated with x-ray.

## Tube housing temperature

Tube housing temperature in Centigrade.

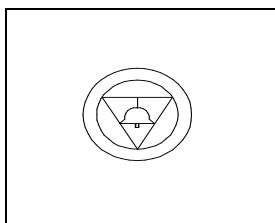
## Exposure counter

Total number of exposures.

## Time and date of last exposure

Time and date of last exposure.

Normal display function is restored pressing pushbutton 12 for few seconds.



## Maximum compression force

According to local laws regulation, maximum compression force can be adjusted up to 150 or 200N. By means of DIP7 SW1 maximum compression force can be selected. Refer to the Service instruction SPB7-115.840.01...

## Functionality tests

### C-ARM vertical movement

Check movement till the upper and lower stop positions.

When at stop position inspect at sight that only first switch MW4 for upper stop or MW3 for lower stop position has been intercepted and movement has not stopped at emergency switch MW2 for upper stop or MW1 for lower stop position.

If emergency switch has been intercepted, c-arm doesn't move anymore and recovery must be done by means of manually turn flywheel of MT1 c-arm motor.

Check functionality of up/down pushbuttons at both sides of the unit

### C-ARM rotation

Check c-arm rotation +/- 180 degrees and functionality of all 4 pushbuttons of rotation handles.

If no image receptor is inserted rotation is disabled as c-arm is not balanced.

If some problem in the c-arm brake occurs system can fall into brake loop and other functions can't be operated. For totally disable c-arm brake set DIP 1 SW2 to ON and have possibility to investigate the problem.

### Compression system

Check that compression trolley moves free by hand when the unit is OFF.

Check insertion of compression paddle.

Check motorized Up / Down movement operated by foot pedal switches.

Check that Collimator lamp goes ON when compression Down is operated.

Check that trolley is free when pressing both foot pedal switches to allow manual compression.

### Cassette detector

When cassette is out of the bucky or cassette holder, green LED of it must blink .

When cassette is properly inserted and unexposed green LED must be bright fix.

### Collimation plates insertion and sensing switch

Check that plates are safely retained and READY label appears on the LCD screen when un-exposed cassette is in the bucky or cassette holder and room door is closed .

### Door switch

If installed, check that READY label appears on the screen when the door is closed and all other devices / functions are ready for exposure.

# Final work steps and protocolar forms

## Final work steps and protocolar forms

### Handling the installation report

The manufacturer of this product requires information and the legislator demands proofs that a system delivered free of defects from the factory continues to possess the required and certified quality properties after installation, start-up and putting-into-operation, (also called: AIAT, standing for: assembly, installation, adjustment and testing).

(The AIAT activities concerned are described in documents:

MAMMOMAT Balance, Installation and Start-up;

Print No: SPB7-115.814.01

MAMMOMAT Balance, Start-up;

Print No: SPB7-115.815.01)

It is therefore absolutely necessary that the Installation report with the installation and start-up data is sent without delay after completion of work to the address stated on the installation report.

You will find the report in the system folder. The Installation report has to be handed over to the responsible project manager (PM), who has to make sure that it will be sent to the address, or fax number, printed on it. It is not foreseen to hand over this Installation report to the customer.

## Changes to previous version

### Changes to previous version

| Chapter                                  | Page | Change |
|--|------|--------|
| Final work steps and<br>protocolar forms | 31   | New    |